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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/027,272 | 12/21/2001 | Stephen L. Crooks | 54913US108 | 3032 |

32692 7590 07/11/2003

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EXAMINER

HUANG, EVELYN MEI

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1625

DATE MAILED: 07/11/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

10/027,272

Applicant(s)

CROOKS ET AL.

Examiner

Evelyn Huang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-43 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 29,30,32,33,35,36 and 38-43 is/are allowed.
- 6) ☒ Claim(s) 31,34 and 37 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Claims 29-37 are pending. Claims 1-28 have been canceled according to the amendment filed on 2-28-2003.

Priority

2. This application claims to be a continuation of 10/166321, filed on 6-15-2001, which is a continuation of 09/589216, now US Patent No. 6331539, which claims the benefit of 60/138365, filed on 6-10-1999.

To receive the benefit of an earlier filing date under 35 U.S.C. 120, the later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994). The examiner is unable to locate 10/166321 to see that this requirement is satisfied. However, the title of 10/166321 is 'A method for the treatment of periodontal disease', such method is not disclosed in 09/589216, and is not described in the instant application. As a courtesy, applicant is requested to send in a copy of 10/166321 with the next response. If this requirement were not met, the instant application would not be entitled to the benefit of the earlier filing date.

Claim Rejections - 35 USC § 112

3. The rejection under 35 U.S.C. 112, first paragraph is maintained for claims 31, 34, 37, for the following reasons, but withdrawn for the other claims in view of the amendment, applicant's remarks and the Brassard reference submitted with the response.

Applicant argues the instant compound induces interferon alpha synthesis, and interferon alpha has been known for decades as an effective anti-neoplastic drug. Brassard is cited by the

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applicant to support the instant method for treating a neoplastic disease with the inventive compound having interferon alpha-inducing activity.

While Brassard, which is published after the filing date of the instant, teaches that interferon alpha administered directly to a patient is effective for treating melanoma, there is no teaching of the use of an interferon alpha-inducing compound in the treatment of a neoplastic disease as recited in the instant. The use of interferon-alpha directly in treating melanoma would not provide the necessary guidance for the instant method of using a compound that induces interferon biosynthesis in vivo, as the two methods require different dosages, different modes of administration, and different pharmacokinetics, especially when 'the anti-tumor activity of interferon alpha against melanoma seems to be a dose-intensive effect' (Brassard, page 572, column 1, last paragraph).

At the time of the invention, little is known about the use of an interferon alpha inducing compound to treat a neoplastic disease, and more guidance would be required for one of ordinary skill in the art to use the claimed invention. The working examples in the specification are limited to in vitro induction of interferon alpha in human blood cells (pages 96-98 of the specification). No in vivo procedures are described. Antitumor activities, in vitro or in vivo, are not found in the specification, without which there is little basis for one of ordinary skill in the art to extrapolate the in vitro interferon-alpha biosynthesis data to the antineoplastic activity, in either in vitro or in vivo situations. Since insufficient teaching and guidance have been provided in the specification, undue experimentation would be required for the skilled in the art to use the inventive compound as claimed.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 31, 34, 37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one

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skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The subgenus of neoplastic disease recited in the claims is not described in the specification. Furthermore, a species example falling within the recited genus is not found in the specification. See MPEP 2163.05.

Double Patenting

5. The cancellation of claims 1-28 has rendered moot the 101 double patenting rejection over US Patent No. 6331539.

6. The claimed method of inducing biosynthesis of interferon alpha in US Patent No. 6331539 is encompassed by the instant method of inducing cytokine biosynthesis. The instant claims should therefore be subjected to obviousness type double patenting rejection over US Patent No. 6331539. However, the timely filed terminal disclaimer has obviated the rejection.

Allowable Subject Matter

7. Claims 29, 30, 32,33, 35, 36, 38-43 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. See paragraph 3 above.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period

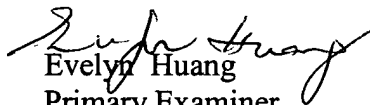
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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 703-305-7247. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on 703-308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


Evelyn Huang
Primary Examiner
Art Unit 1625

June 12, 2003